

ecomì®

(econazole nitrate)

COMPOSITION

100 ml of dermatological milk contain:

Econazole nitrate 1 g

Excipients: Polyoxyethylene glycols mono and dipalmito stearate, Lauro-palmito stearic polyoxyethylene glycerides, Liquid paraffin, Colloidal silica, Lavender essence, Butylhydroxyanisol, Purified water.

100 g of dermatological cream contain:

Econazole nitrate 1 g

Excipients: Polyoxyethylene glycols mono and dipalmito stearate, Lauro-palmito stearic polyoxyethylene glycerides, Liquid paraffin, Benzoic acid, Lavender essence, Butylhydroxyanisol, Purified water.

100 g of dermatological powder contain:

Econazole nitrate 1 g

Excipients: Talc, Zinc oxide, Colloidal silica, Lavender essence.

One vaginal suppository contains

Econazole nitrate 150 mg

Excipients: Semi-synthetic glycerides

10 ml of solution contain

Econazole nitrate 100 mg

Excipients: Lavender essence, Polysorbate 80, Propylene glycol.

One plastic bottle with 150 ml of ready to use solution contains

Econazole nitrate 100 mg

Excipients: Lavender essence, Polysorbate 80, Propylene glycol, Purified water.

PHARMACEUTICAL FORMS

- Dermatologic cream 1% tube of 30 g
- Dermatologic milk 1% bottle of 30 ml
- Dermatological powder 1% ampoule of 30 g
- Vaginal suppositories of 150 mg blister containing 6 suppositories
- Solution of 100 mg for gynaecological use box of 5 ampoules (10 ml)
- Vaginal douche ready to use box of 5 plastic bottles of 150 ml

PHARMACEUTICAL CATEGORY

Antimycotic, antibacterial chemotherapeutic preparation.

OWNER OF MARKETING AUTHORIZATION AND MANUFACTURING COMPANY

GEYMONAT S.p.A. - Via S. Anna, 2 - ANAGNI (FR)

MANUFACTURING COMPANY OF VAGINAL DOUCHE READY TO USE

C.O.C. Farmaceutici S.r.l. - Via per Modena 15 - S. Agata Bolognese (BO).

THERAPEUTICAL INDICATIONS

Dermatological use: cream, milk, powder.
Dermatological infections of mycotic and bacterial origin, susceptible to chemotherapeutic treatment.
Gynaecological use: suppositories, solution, vaginal douche ready to use.
Vulvovaginal infections of mycotic and bacterial origin, susceptible to chemotherapeutic treatment.

CONTRAINDICATIONS

Ascertained individual hypersensitivity to the product.

PRECAUTIONS

During repeated use the inhalation of ECOMI® dermatological powder should be avoided.

INTERACTIONS

From the results of trials carried out, no interactions with other drugs were found.

WARNINGS

The regular use of the product, following the physician's directions is essential for the recovery. During treatment of genital infections the topical treatment of the partner is extremely important in order to avoid "ping-pong" mutual reinfections.

USE DURING PREGNANCY

During pregnancy the product must be administered if effectively needed and under direct medical supervision.

KEEP OUT OF THE REACH OF CHILDREN.

DOSAGE AND ADMINISTRATION

According to medical prescription.

Dermatological use: cream, milk, solution, powder.

Topical applications: smear a thin layer of the product on the infected area of the cutis, rubbing gently; if necessary the area can be bandaged. The treatment can be repeated, if necessary, 1-3 times daily. The choice of the pharmaceutical preparation to be used (cream, milk, solution, powder) depends upon the infected area and on the kind of infection to be treated.

Gynaecological use: suppositories.

To be inserted deeply in situ, in a recumbent position, one suppository each evening for three consecutive days; for particularly resistant infections the treatment can be continued. It is also advisable to apply an adequate quantity of cream on the vaginal opening and on the vulvar surface.

Solution

Such formulation is also meant for vaginal use as "vaginal douche" after dilution with 500 cc of warm water previously boiled. The vaginal irrigation should be done preferably in the morning and in the evening, according to the usual practice, after dilution of the mono-dose ampoule. The presence of the tensio-active substance gives the aqueous solution a foamy aspect whose intensity may vary according to the quality of the water used.

Vaginal douche ready to use.

The cannula should be gently introduced into the vagina. Press the plastic bottle slowly so as to empty it completely. The vaginal douche should be carried out preferably in the evening. A slow irrigation provides a better medical detergent action. If necessary, the concomitant or subsequent use of other topical therapies, their frequency and duration will be established by the physician in charge.

Treatment of the partners

During the treatment of genital infections it is preferable that also the partner undergoes a daily cycle of topical treatment.

ADVERSE REACTIONS

The product is usually well tolerated and adverse reactions have rarely been reported following the use of ECOMI®.

After the use of this kind of preparations for vaginal use, in the first period of treatment the following symptoms were complained: vaginal burning and irritation, pelvic cramps, cutaneous rash, headache, local itching; the occurrence of such symptoms must be reported to the physician in charge, who will decide if the treatment must be interrupted.

The use of pharmaceutical preparations for protracted topical application may cause sensitization phenomena.

In this case it is necessary to withdraw the treatment and the appropriate therapy must be started. The same must be done if the development of microorganisms non susceptible to the product occurs.

Any undesired adverse reaction must be reported to the physician in charge or to the pharmacist.

THE PRODUCT MUST BE USED WITHIN THE EXPIRATION DATE PRINTED ON THE PACKAGE.